

Remarks

Claims 1 and 3-64 are pending. Claims 21 to 64 are newly added. No new matter has been introduced. The specification supports all amendments and new claims. The numbered paragraphs below correspond to the Examiner's numbered paragraphs:

1. Applicants acknowledge the withdrawal of claims 3, 6, 7, 11, 12, 14, 17 and 20. First, Applicants believe that the newly added claims are within the bounds of the elected species. Upon allowance of the generic independent claims, Applicants reserve the right to add new dependent claims directed to the non-elected species. Second, since generic claim 1 is now believed to be in condition for allowance, Applicants respectfully request rejoinder of the withdrawn non-elected species.

2. Applicants believe the amended Abstract is sufficient to overcome the Examiner's concern.

3. Applicants thank the Examiner for pointing out the typographical error. The error has been corrected. Removal of the objection is respectfully requested.

4./5. Claims 1, 5, 8-10, 13, 15, 16 and 19 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Kokish (6,544,223).

With respect to claim 1, Kokish fails to teach, "wherein the inflated state is greater than a range of an intended expanded configuration of the balloon and less than a diameter or size at which the balloon becomes damaged or unsuitable for its intended use for insertion into a patient."

This amendment is a combination of claim 2 and the teaching of page 7, line 22 to page 8, line 1. Not only did Applicants fail to find this limitation in Kokish, but also the Applicants

are assuming that the Examiner is in agreement since the Examiner failed to reject claim 2 under Kokish (claim 2 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Campbell et al. (6,120,447) as applied to claim 1, and further in view of Shannon (6,537,247)).

Accordingly, Claim 1 is now believed to be patentably allowable over Kokish. Claims 5, 8, 9, 16 and 19 depend from claim 1 and are patentably allowable for at least the same reason.

Claims 10, 13, and 15 have been placed in independent form as Applicants respectfully disagree with the Examiner's rejection of these claims under Kokish.

With respect to claim 10, the Examiner has submitted that "the balloon is completely deflated to a flattened configuration prior to the removal of the fluid carrier." The Examiner cites column 7, lines 34-40 ("Example 2") for support of this rejection. Example 2 simply teaches applying a composition to a deflated balloon. Example 2 is not even remotely applicable to claim 10 as it fails to teach "wherein the **balloon is reduced to a deflated state or to a collapsed configuration from the inflated state prior to or during the process of removal of the fluid carrier.**" In other words, Example 2 does not teach inflating a balloon which is later deflated prior to or during the drying process. Moreover, col. 7, lines 23-26 explicitly teach that the balloon is partially inflated not only during the coating process but also during the drying process ("air dry for approximately 4 hours ... with the balloon partially inflated"). Accordingly, the subject matter of claim 10 should have been deemed allowable by the Examiner.

With respect to claim 13, Kokish fails to teach "wherein the inflated state is **maintained** at the same or a generally same level during the removal of the fluid carrier." Again, in col. 7, lines 23-26, Kokish simply teaches that the balloon is partially inflated during the drying process.

Being partially inflated during the drying process is not equivalent to a claimed limitation that the inflated state **is maintained at the same or generally same level.**

Kokish applies a polymeric coating for preventing the “jetting-effect” of a drug out from the balloon. With regular porous balloons, the injection of a drug out from the balloon causes trauma to the vessel walls. Kokish solved this problem by applying a polymeric material to the surface of the balloon. Kokish fails to teach “applying a substance to an outer surface of the balloon, wherein the substance is coated on the outer surface of the balloon and/or is deposited within a wall membrane of the balloon, wherein the substance comprises a therapeutic substance; and reducing the balloon to a collapsed configuration or an under inflated state in preparation for the intended use of the balloon,” as recited by claim 15.

With respect to new claim 21, Applicants submit the following: Kokish coating composition is applied to the outer surface of the balloon. Kokish fails to teach that the composition is deposited within a wall membrane of the balloon as claimed. Although the Kokish balloon is porous, the deposition of the substance within the porous depends on a variety of factors, including the material from which the balloon is made, the viscosity of the coating composition, the surface tension between the coating composition and the balloon material, the duration of exposure of the coating composition to the balloon, the degree of inflation of the balloon, among other variable. Kokish is simply silent with respect to these variables and Applicants respectfully submit that an assumption that the Kokish composition is impregnated within the balloon material would be extremely tenuous.

With respect to new claim 57, Applicants submit the following: Kokish fails to teach “removing the fluid carrier from the balloon such that a dry form of the substance is left on

and/or within the wall membrane of the balloon, wherein prior to or during the removing process, the inflated state of the balloon is modified to a different state.” Again, as indicated above, in Example 1 Kokish teaches that the balloon is partially inflated both during the coating stage and the drying stage. In Example 2, Kokish simply teaches application of the coating composition to a deflated balloon as the balloon is never inflated. Applicants respectfully submit that Kokish does not even remotely teach modification of the inflation state of the balloon prior to or during the claimed fluid removal process.

6. Claims 1, 5 and 8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Campbell et al. Applicants believe that amended claim 1 is now allowable over Campbell et al. because of the following reason:

Claim 1 now includes the limitation of claim 2 and the disclosure on page 7, line 22 to page 8 line 1. The Examiner rejected claim 2 under 35 U.S.C. § 103(a) as being unpatentable over Campbell et al. in view of Shannon. As the Examiner correctly indicated, Campbell does not teach an inflated state that is hyper-inflated or inflated greater than a range of an intended expanded configuration. To cure this deficiency, the Examiner submitted that “Shannon teaches when a balloon does not deflate as desired, a practitioner may over inflate the balloon to intentionally **rupture the balloon wall**, causing immediate deflation of the balloon and enabling withdrawal of the balloon.”

Claim 1 has been amended such that the disclosure of Shannon now teaches away from the claimed subject matter. Claim 1 now recites “**wherein the inflated state is greater than a range of an intended expanded configuration of the balloon and less than a diameter or size at which the balloon becomes damaged or unsuitable for its intended use of insertion into a**

patient.” Shannon’s teaching of rupturing the balloon causes damage to the balloon and makes it unsuitable for insertion into a patient for balloon dilation, drug delivery, stent delivery and the like, as described in the current specification. The combination of Campbell and Shannon not only fail to teach what has been claimed but clearly teach away from the quoted claimed limitation.

Claim 1 is now believed to be patentable over the Campbell et al. and Shannon, individually or in combination. Claims 5 and 8 depend from claim 1 and are allowable for at least the same reason.

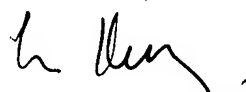
7./8./9. (Examiner’s renumbered paragraphs 1, 2, and 3 under 35 U.S.C. § 103(a)). Claims 2 and 4 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Campbell et al. in view of Shannon. Claim 2 has been canceled. Claim 4 depends from claim 1 as is believed to be allowable by virtue of its dependency.

10. (Examiner’s renumbered paragraph 4). Claim 18 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kokish as applied to claims 1 and 16 above, and further in view of Fukaya et al. (6,613,066). As indicated above, Applicants believe that claim 1 is now allowable over Kokish. Fukaya et al. do not cure the previously described deficiencies of Kokish with respect to claim 1. Accordingly, claim 1 is patentably allowable over the combination. Claim 18 depends from claim 1 and is allowable for at least the same reason.

SUMMARY

Removal of the rejections and allowance of the application is hereby respectfully solicited. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0323.

Respectfully submitted,



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